

REMARKS

Claims 1, 3, 10-12, and 14-51 are pending.

Claim 1 has been amended to specify further that the IRM compound is an agonist of TLR 6, 7, and/or 8 (from original claims 4 and 5).

Claims 2, 4-9, and 13 have been canceled.

Claims 10, 13, and 15-51 are withdrawn from consideration.

Reconsideration of the application is respectfully requested.

§ 102 and 103 Rejections over Gerster, Slade and Miller, and new rejection further in view of Langer.

Claim 1 explicitly requires that the IRM compound be covalently bonded to a macromolecular support (bold added):

An IRM-support complex comprising an IRM compound that is a TLR agonist selected from the group consisting of TLR6, TLR7, TLR8, and combinations thereof, and selected from the group consisting of imidazoquinoline amines; tetrahydroimidazoquinoline amines; and imidazopyridine amines; 1,2-bridged imidazoquinoline amines; 6,7-fused cycloalkylimidazopyridine amines; imidazonaphthyridine amines; tetrahydroimidazonaphthyridine amines; oxazoloquinoline amines; thiazoloquinoline amines; oxazolopyridine amines; thiazolopyridine amines; oxazolophthyridine amines; thiazolonaphthyridine amines; 1*H*-imidazo dimers fused to pyridine amines, quinoline amines, tetrahydroquinoline amines, naphthyridine amines, or tetrahydronaphthyridine amines; and combinations thereof; **covalently bonded** to a macromolecular support material.

Gerster, Slade and Miller do not disclose, expressly or inherently, any IRM covalently bonded to a macromolecule.

The Office Action suggests that polyethylene macromolecules in the Gerster disclosure “could be bonded to the reactive groups on the IRM molecules.” However, that is not correct and the present application does not disclose or suggest covalent bonds form automatically by simply mixing the macromolecules with the IRM compounds. To the contrary, as shown in the present application specific reactions are performed using reactive groups on the macromolecules to result in the desired covalent bonding attachment. Hydrogen bonding, referenced in the Office Action, would not be a covalent bond as required by the amended claims.

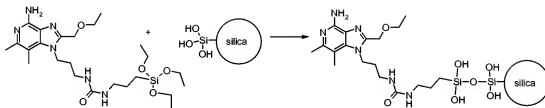
The formulation mixtures of Gerster, Slade and Miller simply do not apply.

The newly cited Langer reference discloses that some drugs can be attached to macromolecules for sustained release. However, it appears from figure D in Langer that the drug becomes active when it is subsequently released. Langer does not teach or suggestion anything about (i) the IRM compounds of the present invention or how they could be attached, or (ii) that the presently claimed IRM compounds can remain functionally active while they are attached to a macromolecule, which is an important and surprising discovery (see, e.g., the Summary, page 1, line 34, to page 2, line 26).

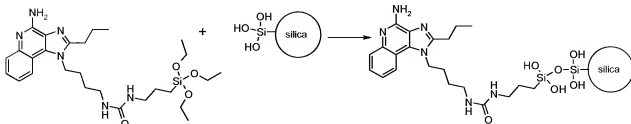
The Office Action states that the prior art teaches “making complexes” of the drug for improving delivery (i.e., sustained release), but the present claims require making covalent bonds and the application discloses the surprising result that the IRM compounds remain active while attached, which allows many important potential uses. Nothing in the prior art provides any such teaching or suggestion or motivation with any expectation of success.

As previously submitted, below are the reaction schemes showing covalent bonding that would be well understood from the examples:

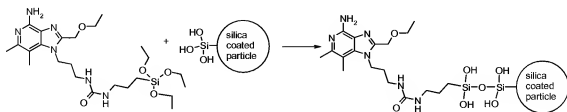
Examples 2 – 6



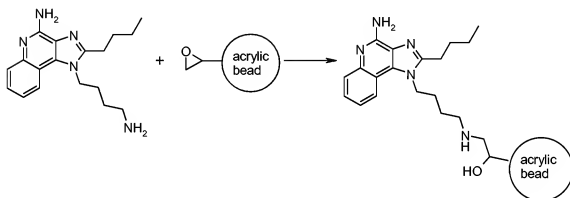
Examples 7 – 11



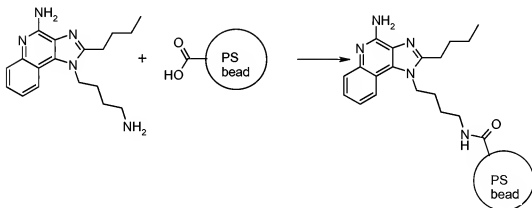
Example 21



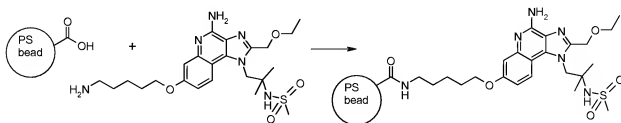
Examples 27 - 29



Examples 30 & 31



Example 32



While the Office Action is correct that many other molecules than those exemplified are included within the claim scope, the amended claims require that the compounds are TLR 6, 7, and/or 8 agonists of specific compound classes. Such molecules thus have both a common structural and functional similarity and one skilled in the art would have no difficulty based on the present disclosure in making additional compounds and covalently attaching them to any number of different macromolecular support materials.

In view of the above, Applicants submit that the rejection under 35 USC § 102 and 103 has been overcome and should be withdrawn.

It is submitted that the application is in condition for allowance. Examination and favorable reconsideration of the application is therefore requested.

Respectfully submitted,

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Date

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